



Element of risk communication: the database for chemical products in italy

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consumer products**

ISS – Rome - Italy

Elements of risk communication:

- ▶ Label
- ▶ Safety data sheet
- ▶ Register for hazardous chemical products (Poison centers)



CLP Label

UNDER THE EU CLP REGULATION THE FOLLOWING CHANGES TAKE PLACE TO THE LABEL:

1. HAZARD (H) STATEMENTS REPLACE RISK (R) PHRASES
2. PRECAUTIONARY (P) STATEMENTS REPLACE SAFETY (S) PHRASES
3. HAZARD PICTOGRAMS REPLACE DANGER SYMBOLS

Product name & Commercial Information

Hazard pictogram

Signal word

Hazard (H) & Precautionary (P) Statements

Transport Information

Methanol

Manufactured by
Company XYZ
Address



Danger

Hazard Statements
XXXXXXXXXXXX
XXXX

Precautionary Statements
XXXXXXXXXXXX
XXXXXXXXXXXX



UN1230 Methanol

Supplemental Information

XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Example of supply & transport label for single packaging - for indicative purposes only pictograms not to scale

CHEMICALS

Safety Data Sheet (SDS)

The requirements for SDS's and guide to the compilation to safety data sheets are set out in Article 31 and Annex II of REACH Regulation 1907/2006 respectively.

SDS's are an important communication tool in the supply chain, helping all the actors in the chain to meet their responsibilities in relation to the management of risks arising from the use of substances and mixtures.

SDS's must be

- Compiled in accordance with Annex II of REACH
- 16 mandatory headings
- All sections completed – not generic
- All information must be consistent with registration
- An official language of member state
- Up-to-date
- Date of issue on first page
- Upon revision, "revision date" to be added
- Clear and concise

- Section 2: Hazards identification
- Section 3: Composition & information on ingredients
- Section 4: First Aid measures
- Section 5: Fire-fighting measures
- Section 6: Accidental release measures
- Section 7: Handling and storage
- Section 8: Exposure controls/personal protection
- Section 9: Physical and Chemical properties
- Section 10: Stability and Reactivity
- Section 11: Toxicological information
- Section 12: Ecological information
- Section 13: Disposal considerations
- Section 14: Transport information
- Section 15: Regulatory information
- Section 16: Other information

The SDS 16 headings are:

- Section 1: Identification of substance or mixture and company

The national register for chemical products in Italy



ELEMENTS OF THE DATABASE



- **Location:** ISS - National Centre for Chemical Substances
- **Scope:** Collecting the full chemical composition for all dangerous preparations marketed in Italy and falling in the scope of CLP. Detergents included later (art. 9 of reg. 648/2004)
Establishing a surveillance system based on collected information about dangerous exposures

Requirements of Art. 45 CLP

- MS shall appoint body or bodies responsible for receiving information on mixtures classified as hazardous on the basis of their health or physical effects
- Appointed bodies shall keep information confidential
- Harmonization of information



Information may be used:

- For medical purposes, in particular in event of emergency
- Where requested by MS, for statistical analysis to improve risk management measures, if needed
- Resulted in different provisions/procedures/requirements by MSs



National Database of Dangerous Preparations



- Art. 10 of the D.Lgs. N. 285/98 (implementing in Italy dir. 88/379) appoints ISS as the Governmental Organization charged for receiving information on marketed Dangerous Preparations, with particular reference to the full chemical composition.
- This provision is confirmed by the D.Lgs. N. 65/2003 implementing in Italy the Dir. 1999/45/EC.

National Database of Dangerous Preparations”

Establishing a Database of Dangerous Preparations listing the dangerous preparations present on National market, to be used only in view of preventive or therapeutic measures, particularly in emergency;

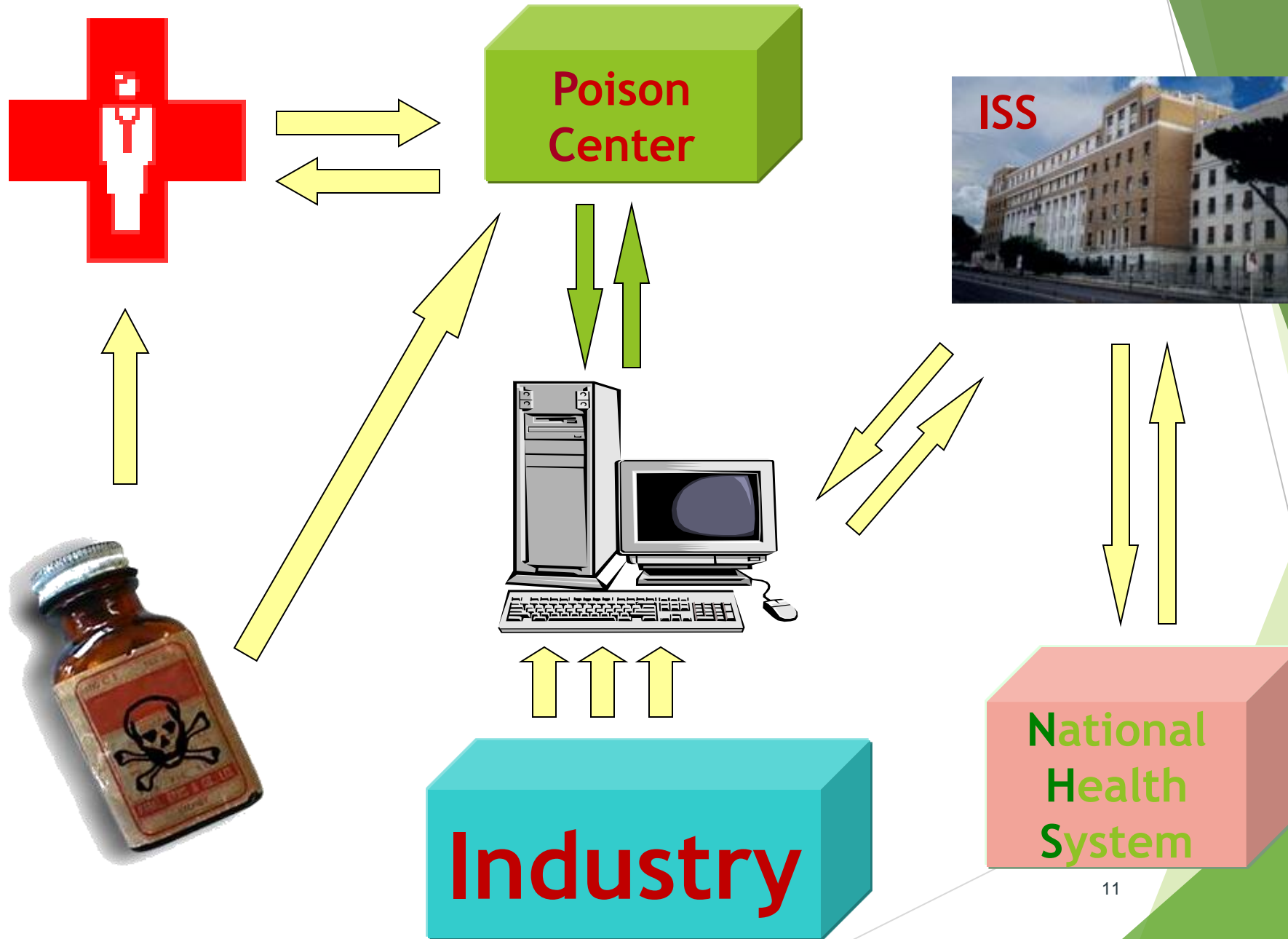
Allowing the on-line consultation of the data bank only to the Poison Centres certified as suitable (9 PCs) by fulfilling specific criteria concerning their structural and human resources, and being able to ensure the confidentiality of the sensitive data with the use of personalized keys of access ; all the other Poison Centres can access the information through the certified Poison Centres;



Detergents

As requested by Art. 3 comma 1 of national D.P.R. 6 Feb 2009, n. 21 concerning implementation of Reg. (CE) n. 648/2004 31 March 2004 about detergents, technical sheets including the list of ingredients should be provided to the national database (Art. 9 Par. 3 Reg. 648/2004 following the specification of Annex VII part C as modified by Reg. 907/2006, 20 June 2006)





National Poison centres

- ✓ Niguarda (MI)
- ✓ Careggi (FI)
- ✓ Maugeri (PV)
- ✓ Policlinico (RM)
- ✓ Gemelli (RM)
- ✓ Cardarelli (NA)
- ✓ CAV Bergamo (BG)
- ✓ Azienda Osp. Foggia (FG)
- ✓ Bambin Gesù (RM)

- **79 Medical staff involved**
- **70 Regional Enforcement people involved**

PURPOSES OF THE DATABASE

“The information contained in the database are confidential and will be used only for health purposes in view of preventive or therapeutic measures to be adopted, particularly, in emergency”.



WHO ARE THE USERS

The system is operational 24 h/day and 7 days/week.

Direct connection for consultation is granted only to the national **Poison Centres** certified by the Ministry of Health as suitable by fulfilling specific criteria concerning their structural and human resources, and being able to ensure confidentiality about data contained in the database.

On a case by case basis, the ISS may give the information to **other central or regional bodies for their institutional tasks (e.g. inspections, control, prevention, accidents etc.)**.

Currently, **9 Italian Poison Centres** have been granted direct access to the database



WHO MUST REGISTER



Those responsible for marketing in Italy dangerous preparations and detergents (classified or not as dangerous) **must send** to the ISS information on these preparations (mainly the **full chemical composition**).

Actors:

- **Producers** (even those who produce elsewhere in the EU and market in Italy directly without traders)
- **Importers** from third Countries (even those who import elsewhere in the EU and market in Italy directly without traders)
- **Traders** of preparations produced in the EU who change the label for the Italian market (e.g. including their name)

ISS guarantees the industry, about the confidentiality of the information stored in the database.

WHICH KIND OF INFORMATION IS REQUIRED

- Name/Address, Tel./Fax., e-mail of Registrant (mandatory)
- Trade name of the products (mandatory)
- Intended uses (mandatory)
- Physical state (mandatory)
- Ph (mandatory)
- Other physico-chemical properties (optional)
- Full quali-quantitative chemical composition (mandatory)
- CLP C&L
- Packaging description (optional)



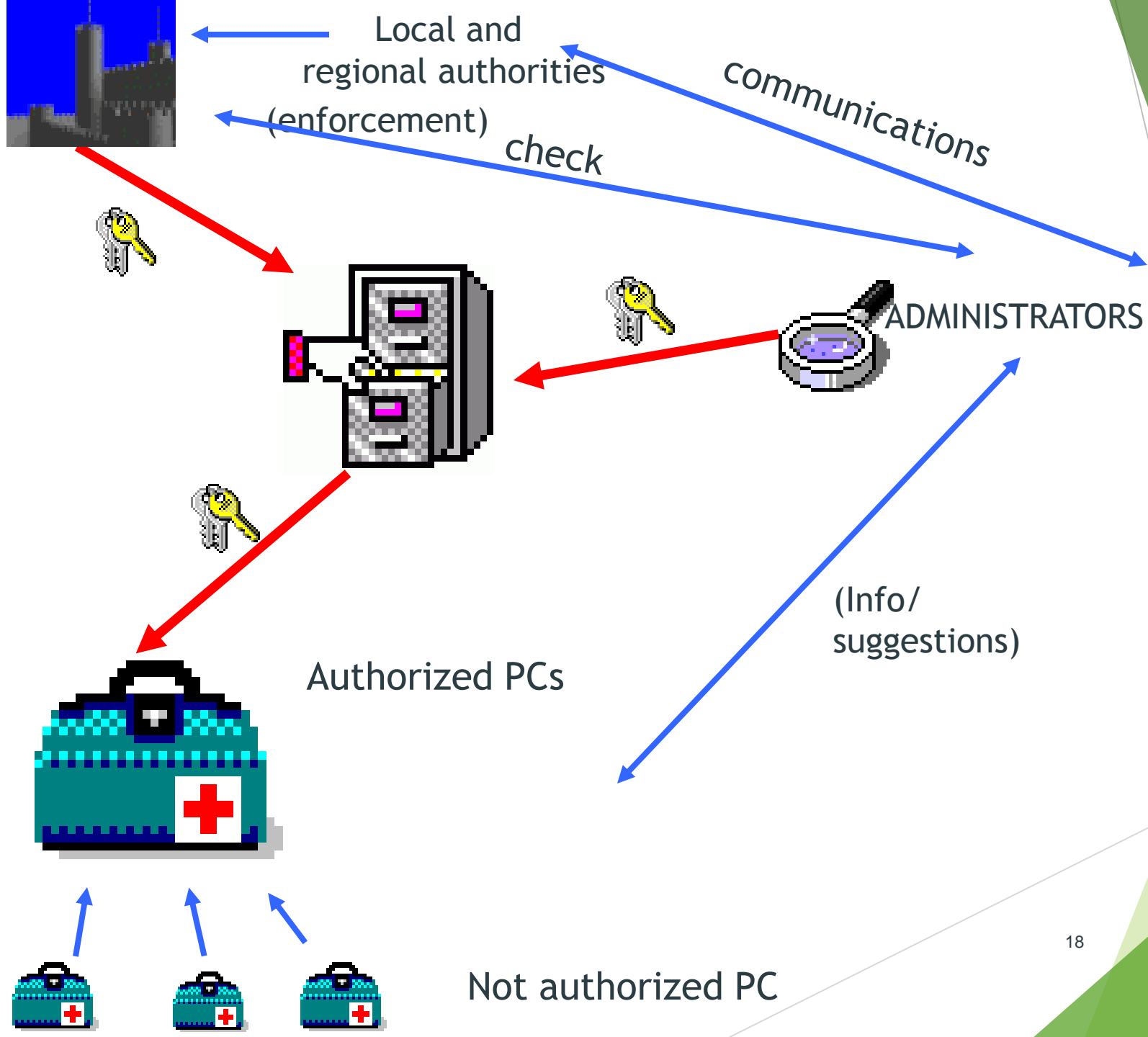
Each registrant has assigned a “company code” and each preparation has assigned a “product code”
A payment of 50€ per year/per registrant is required

DEADLINES

New preparations:



Currently, for the dangerous preparations put on market for the first time in Italy, the registration to the database must be performed within **30 days** as from the date of introduction into the Italian market.



Consultazione database

Ricerca Azienda

Per cercare dati anagrafici delle aziende registrate.

Nome dell'azienda

> Cerca

Reset

Ricerca Preparati

Nome del preparato:

Anche come sinonimo

NOTA: Il sistema cerca qualsiasi sottostringa all'interno del Nome.

Per cercarne solo l'inizio, specificare * alla fine della stringa (ES: **Dixa***, **vernic***, ...).

Codice del preparato:

Nome dell'azienda:

Codice dell'azienda:

Solo preparati **Detergenti**

> Cerca

Reset

->Toggle<-



User: lpennisi [Logout]

Ruolo: CAV

[Home Page](#)

[Consultazione database](#)

[Profilo personale](#)



**Number of preparations in National
database: 2.155.019 (28.2.2018)**

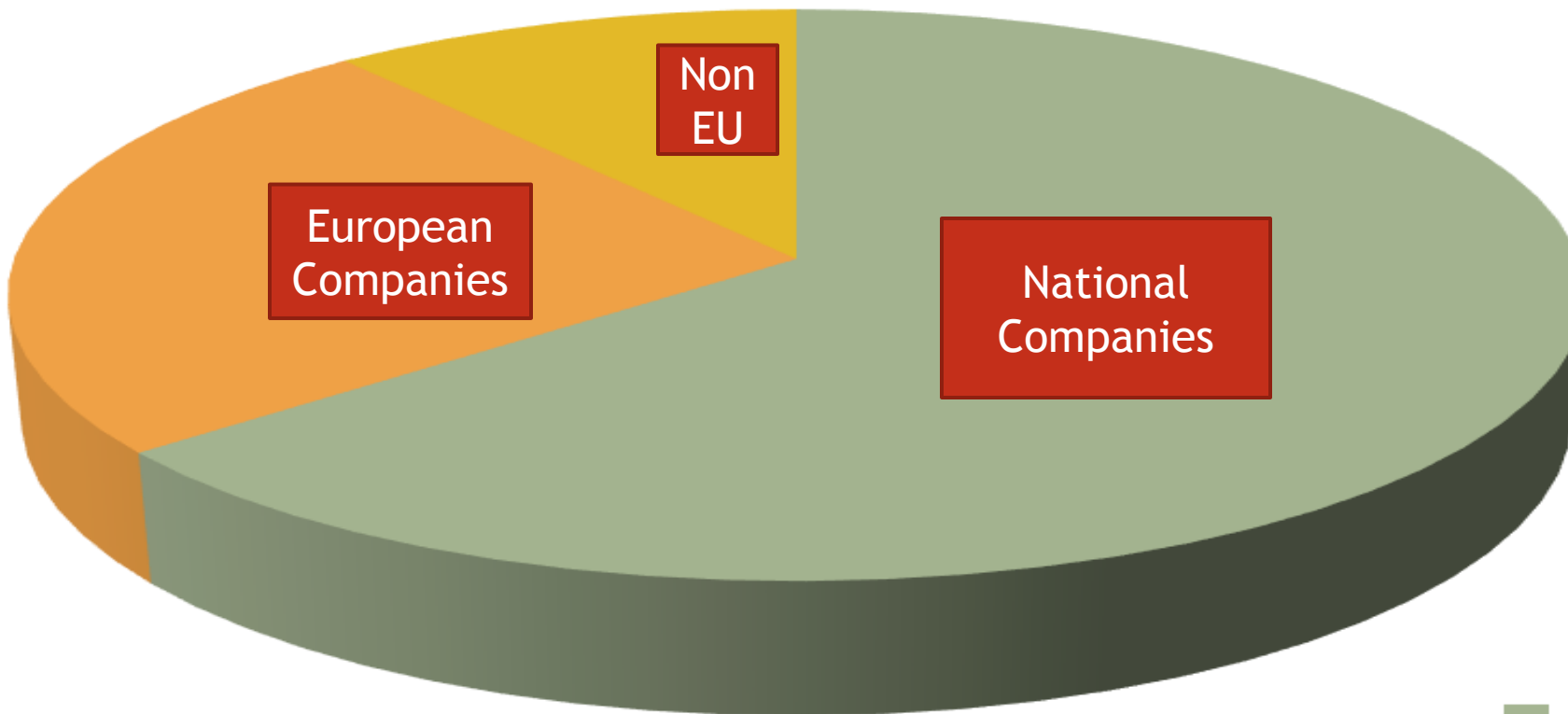
**Dangerous preparations (not
detergents): 2.092.334**

Detergents: 62685

**N. of PCs enquiries (02-01-2017 -
31.12.2017) : 9425**

Status

2017



Applicant : 5922

- Az. Italiane
- Az. Europee
- Az. ExtraEU

European Notifiers



AUSTRIA	18
BELGIUM	52
BULGARIA	1
CROATIA	1
CZECH REPUBLIC	3
DENMARK	8
ESTONIA	1
FINLAND	5
FRANCE	96
GERMANY	330
GREECE	1
HUNGARY	2
IRELAND	4
ITALY	4190
LUXEMBOURG	2
NETHERLANDS	76
NORWAY	1
POLAND	1
PORTUGAL	1
SAN MARINO	4
ROMANIA	1
SLOVENIA	1
SPAIN	52
SWEDEN	8
SWITZERLAND	32
TURKEY	1
UNITED KINGDOM	85



Extra UE

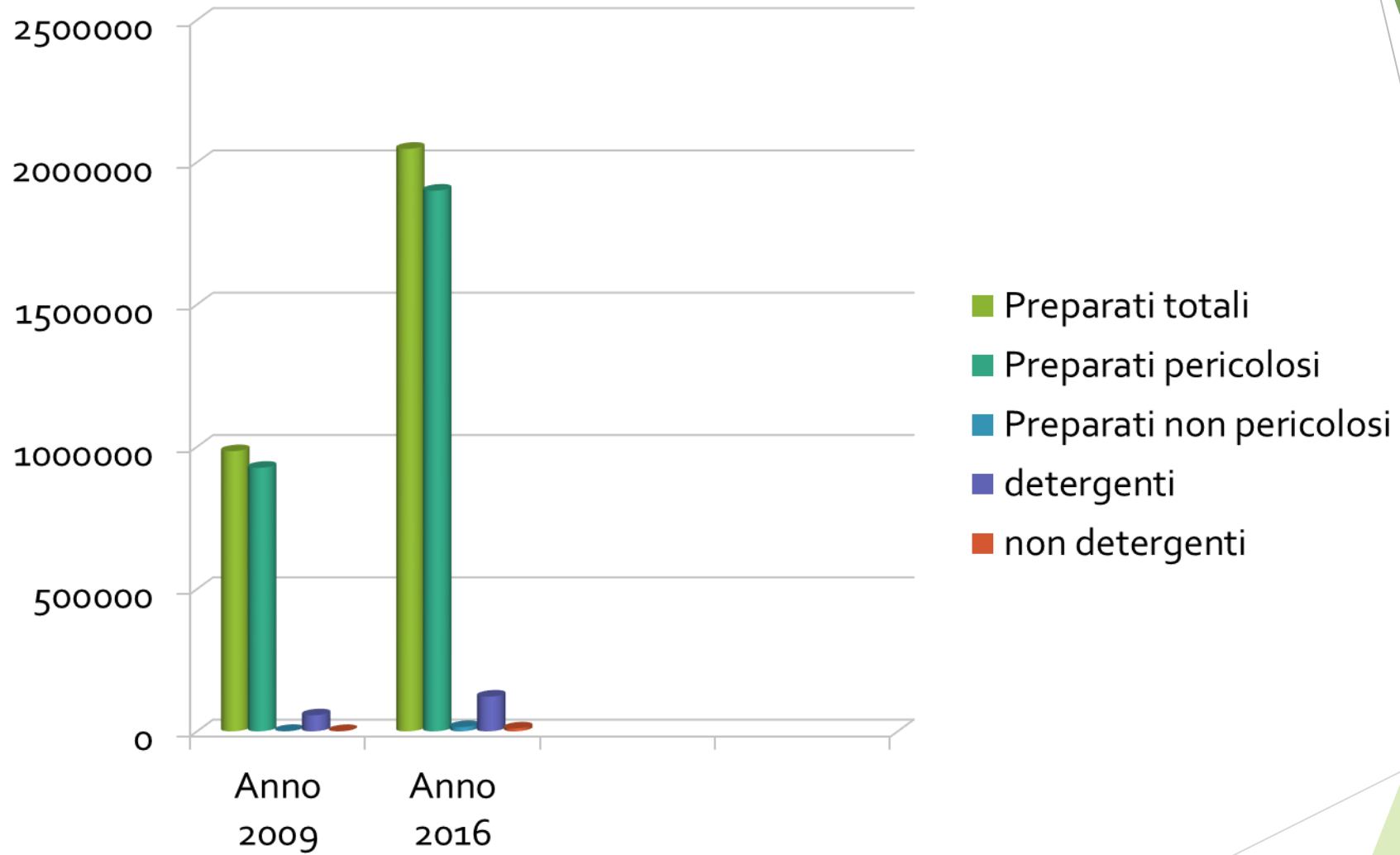


USA
ARGENTINA
JAPAN
CHINA
INDIA
CANADA

20
1
2
1
2
3



Trend 2009 - 2016



BUGS

- ▶ Mixtures where compositions does not reach 100%
- ▶ Mixtures where some ingredients are linked to ingredients directly notified by producers (confidentiality) but this link does not work
- ▶ Mistake due to wrong C&L of the ingredients
- ▶ Mistake due to wrong responsibility of notifiers/importers/distributors
- ▶ Mixture in mixture : difficulties to link



New commercial «products»

▶ Clinker concrete



▶ E-cig mixtures



New commercial «products» (1)

New commercial **Mixtures for refilling e-cigarette**

- Mixtures mainly imported from UE
- 42 notification since 2013
- Ignorance about legal requirements, mostly from simple importers
- Uncorrect C&L notification («explosives»!!)
- Some accidents due to accidental ingestion (mistake due to similarity to pharmaceutical products), mainly in children



New commercial «products» (2)

E-cig mixture classifications as proposed by Notifiers

- Toxic by ingestion
- Toxic by inhalation
- Toxic by contatto
- Harmful
- Explosive (!)
- Sensitizers
- Irritating
- Dangerous for environment



New commercial «products» (3)



Klinker - Concrete



- Different mixtures, very often linked to several availability of ingredients
- High variability of mixture
- Million of producers
- Different degrees of dangerousness, linked to % dangerous components

New commercial «products» (4)

Klinker – Concrete

<u>Percentage</u>	<u>Mixture</u> <u>CLP Classification</u> <u>(concrete)</u>	<u>Indication of danger</u>
Clinker concrete > 5 % and < 20 % by weight	Eye Dam. 1; H318 Skin Irrit. 2; H315 Skin Sens. 1; H317	H318 Severe eye damage H315 Skin irritant H317 Can cause skin sensitization  

CLP impact on databases workload

The impact resulted from the application of the CLP has also inevitably led to an increase of the workload for national databases for poison centers, both for Applicants and Operators



Category of Danger	Concentration limit for classification
Acute oral toxicity 1*	0.025%**
Acute oral toxicity 2*	0.25%
Acute oral toxicity 3*	5%
Acute oral toxicity 4*	25%
STOT 1	1%
STOT 2	10% (but needs SDS on request at 1%)
Skin corrosion 1	5% (becomes Cat 2 skin)
Skin corrosion 1	3% (becomes Cat 1 eye)
Skin corrosion 1	1% (no classification)
Skin irritation 2	10%
Skin or respiratory sensitiser	1% (but needs SDS on request at 0.1%)
CM Cat 1a, 1b	0.1%
R Cat 1a and 1b	0.3% (but needs SDS on request at 0.1%)
CM Cat 2	1% (but needs SDS on request at 0.1%)
R Cat 2	3% (but needs SDS on request at 0.1%)
Aquatic acute 1	0.1% ****
Aquatic chronic 1	0.1% ****
Aquatic chronic 2	1%
Aquatic chronic 3	10%
Aquatic chronic 4	1 %***
* Based on ATE point estimate in Table 3.1.2,	
** Note that if below limit of concern of 0.1% for Cat 1, the legal text implies that substances can be ignored unless it is known to be of concern. Rather vague !	
*** Consider on case-by-case, especially if potential vPvB or PBT.	
**** Note M factor	

-DPD : 20 %

-DPD : 5 %

Note that the text of the CLP Regulation covers this in detail and this is a summary of limited endpoints.

CLP: impact on detergents

Household products	EU	CLP (all cats.)
Laundry detergent (powder)		
Skin irritant	22%	100%
Eye irritant	100%	100%
Laundry detergent (liquid)		
Skin irritant	84%	100%
Eye irritant	100%	100%
Cleaning fluids		
Skin irritant	15%	100%
Eye irritant	65%	100%
Dishwashing liquid		
Skin irritant	88%	100%
Eye irritant	100%	100%

**Serious Eye Damage / Eye Irritation:
Implications of CLP**

Source: AISE

Table 2.4 Number of companies by sector across the EU based on Eurostat data
 companies in 2011 (most recent complete year).

Sector	Large sized	Medium Sized	Small Sized	Micro Sized	Total
Industrial Gases	22	51	118	257	448
Dyes and Pigments	30	75	151	358	614
Basic Inorganics	51	135	260	597	1043
Basic Organics	107	258	529	1139	2033
Fertilisers	63	155	311	764	1293
Pesticides and Agrochemicals	30	78	152	374	634
Paints and Varnishes	146	534	1181	2314	4175
Soaps and Detergents	78	299	707	2682	3766
Perfumes and Toiletries	95	353	828	3137	4413
Adhesives	31	79	155	359	624
Chemical production (Not Otherwise Covered)	92	470	1054	2797	4413
Total	745	2487	5446	14778	23456

ASSIC 18.3.2015

HOW WE SEE THE FUTURE OF THE NATIONAL DATABASES AND THE NEW EU REQUIREMENTS

- The Poison Centres usually don't need extended info on the preparations (e.g. the full content of SDS), and prefer to get an essential and quick info useful for their institutional activity
- Now identified a core set of data which are essential for the Poison Centre and which are present (but sometimes different) in the different national databases
- On the basis of such "core set of data" we strongly welcome the common format in an electronic platform compatible with all the systems adopted in the different MS
- Such common format is satisfying the requirements of all national databases, so avoiding for the industry to be obliged to fill up different forms for the different national databases
- A more long-term project could aim at allowing the different national databases to be connected with each other in an European Network so as to widen for the Poison Centres the research possibilities in case of need.
- This could be anyway achieved by the introduction of the UFI and categorization system.
- We face the additional workload for next 5 year in which old and new systems will work in parallel
- ECHA is evaluating the opportunity of a central database, not very welcome by some EU countries (DE, IT, ecc)

National activity for acute exposure/poisoning reporting

- ▶ Several pieces of legislation related to chemicals provide specific risk mitigation measures to be applied by risk assessors, in order to warrantee the safe use of a chemical product.
- ▶ Current legislations, in particular those related to authorization procedures, take into account solely exposure scenarios referable to the only “safe use” of a product.
- ▶ Unfortunately, exposure cases (mostly for non-professional exposure) are reporting intoxication cases due to accidental exposure or misuse.

The new national project

- ▶ This project is related to the real time gathering of cases due to dangerous products exposure or intoxication, as reported by poison centers.
- ▶ Monitoring of access to the national database could be helpful for establishing a correlation between dangerous products and exposure cases
- ▶ In particular, the correct choice of products categorization as well as specific population groups are described, with particular attention to sensitive population such as children, elderly, pregnant women.

The new national project (2)

- ▶ A new pilot project has been launched in 2016 and a network with national scope has been in progress according to the following:
 - Calls from users to PCs should be made according to regional criteria or within the Region of origin of the person reporting;
 - Reserves on the possibility of activating a single toll-free number;
 - PCs report (which already provide an annual activity report that is requested and partially funded at regional level) should be harmonized;
 - Data transmitted by the individual PCs should be harmonized in content and format.
 - Avoid a duplication of the work of the Pcs.

The following short-term actions of the pilot project are now agreed at national level:

- Transmission of data from PCs to ISS;
- Harmonization of the criteria for reporting, also based on the document prepared by the National Center for Chemicals / ISS, distinguishing between telephone call and First Aid on site;
- Formalize and rationalize data collection through the preparation of an annual report, also aimed at obtaining funding for this activity.
- Format of reporting should be consistent to the Art 45 (CLP), in order to fulfil the new EU requirements (eg: new categorization scheme)
- The new format for reporting accidents has been already presented

Long-term actions will include:

- Possible specialization of PCs;
- Presentation of the national project and possibly extension to all PCs
- First report feedback

Methomil intoxication case : reporting by PC Foggia*

- ▶ "Accidental" exposure poisoning: ingestion of methomil incorrectly contained in a bottle for food consumption (water)
- ▶ Research in the database revealed obsolete products probably still on the market
- ▶ Product containing emetic substances (sucrosooctaacetate) obliged by the same directive for inclusion of methomil, binding indication to the marketing.
- ▶ First Aid Information "If swallowed, it may be helpful to induce vomiting in the following circumstances: only if the person is conscious, within 30 minutes of ingestion, if there is no seizure."
- ▶ This procedure is not recommended by the PC experts because it would lead to a second passage of the toxic with possible pulmonary aspiration: in case of corrosive substance to a second gastro-esophageal passage with possible lung damage and in case of hydrocarbons with chemical pneumonia.

* This case will be presented at SITOX 2018 (Bologna, Italy, 10/13.4.2018)

Ricine animal intoxication case: reporting by PC Milan Niguarda

- ▶ Two fatal cases of dog intoxication by ingestion of a «natural» product containing Ricine
- ▶ Product sold in a fraudulent way with the dual claim of fertilizer and biocide repellent
- ▶ Product sold in as free market product
- ▶ Ricine not included in the biocide review program
- ▶ Several similar products included in the national databases, now removed from the market
- ▶ Products were not correctly labelled
- ▶ Also SDS presented several mistakes and or omissions

Methanol intoxication case: reporting by PC

Pavia

- ▶ Abuse" exposure intoxication: voluntary ingestion of denatured alcohol contaminated with 20% methanol.
- ▶ Denatured alcohol produced in Italy but sold in a Chinese store.
- ▶ Original Italian products correctly registered in the national database
- ▶ The original Italian product did NOT contain 20% of methanol but only 4%
- ▶ Fatal outcome



The FIPRONIL case

Authorized as :

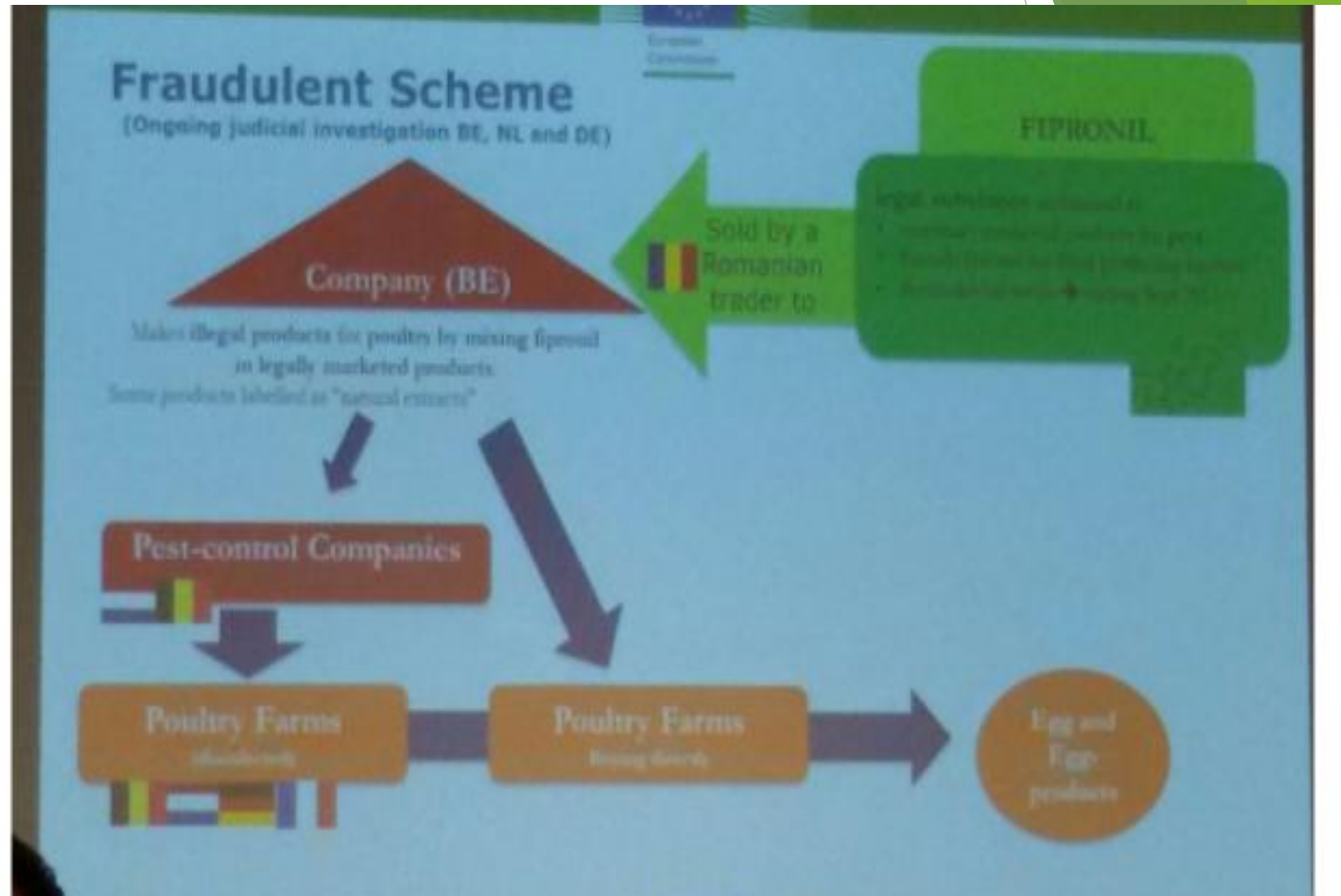
- ▶ Veterinary product for ectoparasites in pets
- ▶ Plant protection product in seed treatment
- ▶ Biocidal product for stables

Forbidden use on livestock

Found in eggs and poultry meat in several EU Countries



The fipronil case



The reported intoxication cases

- ▶ The clinical case of poisoning has been of fundamental importance from a medical point of view and for the management of the intoxication, but also for the network between risk assessors, regional and national authorities and PCs
- ▶ The feedback of an intoxication in an emergency could result of an improvement of the management and risk mitigation measures for a greater protection of human and animal health .
- ▶ A possible improvement of labels, packaging and SDS and a greater protection of potential customers.
- ▶ The importance of creating a network that makes it possible to provide the information flows deriving directly from poison centers

Conclusions

- ▶ Risk assessment is a complex process and still presents uncertainties, but still guarantees a high level of protection for man and the environment
- ▶ It does not take into account the incorrect or fraudulent use and the methodologies for the estimation of cumulative or synergistic effects or due to multiple exposure are still uncertain.
- ▶ The importance of the timely collection of reports, in addition to being provided for by various European regulations on chemical safety (Biocides, PPPs and Art 45 CLP Regulations), is important for the development of risk containment strategies that can be have been underestimated at the time of initial risk assessment (eg detergent single-dose capsules, water-based gel sanitizing agents, now revised following the numerous reports of accidental exposures).
- ▶ Hence the importance of the collaboration between Poison Centers, ISS and Ministry of Health for the early identification of additional risk containment / management measures elaborated on the basis of the exposure series.

Thank you!



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